

**PRODUCT:** 1 *Vapo-Path* (device) with appliances and various drugs and a number of leaflets entitled "Be a Millionaire In Your Home Town" and booklets entitled "Vapo Path Must Be Good" at Washington, D. C.; also 1 *Vapo Path* (device) with similar appliances and drugs and a number of booklets entitled "Vapo Path Must Be Good" at Murray, Ky.

The device consisted of an electric- or gas-heated, thermostatically-controlled generator and the following appliances: Bath cabinets, metal and canvas masks, enamel and metal foot and leg baths, metal hoods for applying vapor locally to the body, plumbing connections and fittings, and a trough to collect condensed vapors. With the outfit seized at Washington, D. C., were 2 electrically-heated vaporizers called "Vapo Aids." The drugs contained minerals and volatile substances.

Steam produced in the generator would pass over various plates containing the drugs, and it was alleged in the labeling that the steam would "Steam Distill" the drugs. The appliances were for the purpose of applying this steam to the part to be treated. The vapors would become permeated with some of the volatile substances, principally naphthalene, but would contain no minerals.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the accompanying leaflets entitled "Be a Millionaire In Your Home Town" and the booklets entitled "Vapo Path Must Be Good" were false and misleading. These statements represented and suggested that the device and the drugs would be effective for arthritis, diabetes, poor elimination, poor circulation, lack of minerals in the body, illness, abscess on the lung, continuous cough, sleeplessness, loss of weight, rheumatism, disease of the stomach and kidneys, bad heart conditions, muscular rheumatism, accumulation of poisons in the system, improper elimination, inflammatory rheumatism, nervousness, stiff joints, melancholia, blood poisonings, swelling of eyes, hands, and knees, infection of the sciatic nerve, acidosis, rash, abscesses, high and low temperatures, decay of the jawbone and sinus, poison in the system, slow kidney action, acid condition, lazy liver, bloating, hay fever, incurable, hopeless, and serious physical conditions, illness in general, numerous conditions of almost every description, and whatever is wrong. The statements in the labeling represented further that the articles would be effective for straightening out the difficulties with which the human system may be struggling, would supply those elements in which the body may be deficient, would attack the basic cause of the vast majority of ailments, and would be effective to prevent serious illness, correct improper conditions, keep one fit, buoyant, and in good health, supply beneficial mineral fumes, and correct deficiencies of the human system. The device and drugs would not be efficacious for the purposes represented and suggested.

**DISPOSITION:** August 16 and November 13, 1946. Vapo Path, Inc., Dayton, Ohio, having appeared as claimant in both actions, and Miss Frances Bradley having appeared also as claimant in the Kentucky action, and the claimants having consented to the entry of decrees, judgments of condemnation were entered and the articles were ordered released under bond to be destroyed or brought into compliance with the law, under the supervision of the Federal Security Agency.

**2140. Pso-Ridisal. Suit for injunction. Fred B. Collier and Dianne I. Collier (Nu-Basic Products Co.) v. Paul V. McNutt, Federal Security Administrator, et al. Complaint dismissed.**

On September 20, 1944, Fred B. Collier and Dianne I. Collier, trading as the Nu-Basic Products Co., at Royal Oak, Mich., filed a petition for an injunction against Paul V. McNutt, Federal Security Administrator, Paul B. Dunbar, Commissioner of the Food and Drug Administration, and George P. Larrick, Acting Commissioner of the Food and Drug Administration. The complainants petitioned that the defendants and their agents be restrained and enjoined from instituting legal proceedings with respect to the complainants' product known as *Pso-Ridisal*.

A motion to dismiss the action and for summary judgment was filed on behalf of the defendants. On November 7, 1944, the court entered an order granting such motion, and in connection with such order, made the following findings of fact and conclusions of law:

MATTHEW F. MCGUIRE, *District Judge:*

## FINDINGS OF FACT AND CONCLUSIONS OF LAW

"This cause having come on to be heard on plaintiffs' motion for a preliminary injunction, and defendants' motion to dismiss the action and for summary judgment, the Court hereby files its Findings of Fact and Conclusions of Law as follows:

## THE COURT FINDS

"1. The plaintiffs are, and were during the times mentioned in the petition for injunction, the owners of the Nu-Basic Products Company, which manufactures and sells in interstate commerce a drug product known as Pso-Ridisal for external use for diseases of the skin.

"2. The said drug consists of a mineral oil emulsion, sulfanilamide, carbolic acid (phenol), and other ingredients, and has been introduced into interstate commerce under the names Sulfa-Seb and Sulfa-Ped, as well as under the name Pso-Ridisal.

"3. On January 21, 1942, a shipment of Pso-Ridisal was seized pursuant to a libel of information filed by the Government under the Federal Food, Drug and Cosmetic Act in the United States District Court for the Northern District of Illinois. The libel alleged that the drug was misbranded because its labeling was false and misleading. The plaintiffs herein appeared as claimants of the seized article, and by consent a decree of condemnation based on said misbranding was entered on April 12, 1944.

"4. On January 28, 1944, a shipment of Pso-Ridisal was seized pursuant to a libel of information filed under the said Act in the United States District Court for the Western District of Missouri. The libel alleged that the drug was misbranded because its labeling was false and misleading. The plaintiffs herein appeared as claimants of the seized article, said action was thereafter removed to the United States District Court for the Northern District of Illinois, and said article so seized was condemned by consent decree of condemnation based on said misbranding on April 26, 1944.

"5. On November 10, 1943, shipments of said drug bearing the names Sulfa-Seb and Sulfa-Ped were seized pursuant to a libel of information filed under the said Act in the United States District Court for the Western District of Missouri. The libel alleged that the drug was misbranded because its labeling was false and misleading and because its labeling failed to bear adequate warnings against unsafe dosage or methods of use in a manner and form necessary for the protection of users. After trial, the said Court, on April 3, 1944, entered a decree based on said false and misleading labeling condemning the labeling of said drug.

"6. After the entry of the decrees above mentioned, applications were made by plaintiffs herein to the courts in which said actions had been filed praying that the seized articles be delivered to them to be brought into compliance with the provisions of the Federal Food, Drug, and Cosmetic Act under the supervision of an officer or employee of the Food and Drug Administration, which applications were granted upon the execution of sufficient bond conditioned as required by law. Thereafter, the plaintiffs herein submitted to the Food and Drug Administration for approval a proposed form of labeling to accompany the seized articles, which form of labeling the Food and Drug Administration, after due consideration, did not approve.

"7. Thereafter, the plaintiffs herein continued distributing its product in interstate commerce under the name Pso-Ridisal accompanied by labeling differing in minor respects from that which had accompanied the said drug involved in the actions above mentioned.

"8. On or about June 13, 1941, the Federal Security Administrator delegated to the Commissioner of Food and Drugs authority to make determinations of probable cause under Section 304 (a) of the said Act (21 U. S. C. 334 (a)).

"9. On July 29, 1944, the Commissioner of Food and Drugs determined that he had probable cause to believe, and that he did believe, on the basis of facts found by employees and officials of the Food and Drug Administration, that the labeling of said drug Pso-Ridisal would be and was in a material respect misleading to the injury or damage of the purchaser or consumer. Thereafter, a number of seizures of said drug with such labeling

were made pursuant to libels of information filed in different district courts of the United States.

"10. The plaintiffs herein, from the filing of said libel actions last above mentioned until the argument on plaintiffs' motion for a preliminary injunction and defendants' motion to dismiss this action and for summary judgment, did not, pursuant to Section 304 (b) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 334 (b)), apply to the court of one jurisdiction wherein one of said libel actions had been brought for an order consolidating all of said libel actions for trial in a district selected by the plaintiffs herein where one of such libel actions was pending.

"11. One of said seizure actions last above mentioned was commenced by the Government in the United States District Court for the Western District of Missouri, entitled 'United States v. 1233 Bottles Pso-Ridisal'. The plaintiffs herein appeared as claimants in said action and by motion filed on or about September 8, 1944, sought to have said action dismissed on the ground that other seizure actions involving said drug and founded on the same or similar allegations of misbranding were already pending in other district courts of the United States. The said District Court denied said application on September 16, 1944.

"12. On or about September 8, 1944, the plaintiffs herein filed in the United States District Court for the Western District of Missouri an action entitled 'Fred B. Collier et al. v. The United States of America, Federal Food and Drug Administration', praying an injunction restraining the further seizure of shipments of said drug. Said action was dismissed by said District Court on plaintiffs' motion on September 9, 1944.

"13. On or about September 16, 1944, the plaintiffs herein filed an action in the United States District Court for the Northern District of Illinois, entitled 'Fred B. Collier et al. v. Paul V. McNutt, Federal Security Administrator', praying that the said Administrator be enjoined from instituting a new libel proceedings against said drug Pso-Ridisal and from harassing or interfering with the plaintiffs' business. Said action was dismissed on motion of the plaintiffs on or about September 29, 1944.

"14. On or about September 20, 1944, the plaintiffs herein filed a petition in the United States District Court for the District of Columbia against the defendants herein seeking to restrain and enjoin them from instituting new libel proceedings and from further seizures of the product Pso-Ridisal, and from harassing and interfering with plaintiffs' operation of their business and the business of their distributors and dealers and from instituting any action based upon the same alleged misbranding which was the subject matter of the proceedings already instituted against the plaintiffs' said product; and prayed that a preliminary injunction be granted.

"15. On or about October 16, 1944, the defendants herein moved to dismiss this action and for summary judgment on the grounds that the petition of plaintiffs herein failed to state facts which entitled plaintiffs to the relief sought therein, and that this Court did not have jurisdiction of the subject matter of this action.

#### THE COURT FILES THE FOLLOWING CONCLUSIONS OF LAW

"1. On or about June 13, 1941, the Federal Security Administrator, pursuant to the authority vested in him by law, delegated to the Commissioner of Food and Drugs, Federal Security Agency, authority to make determinations of probable cause contemplated by Section 304 (a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 334 (a)).

"2. The institution of multiple libel for condemnation actions against plaintiffs' product Pso-Ridisal was authorized by law inasmuch as the Commissioner of Food and Drugs of the Federal Security Agency had determined, pursuant to said Section 304 (a) of said Act (21 U. S. C. 334 (a)), that he had probable cause to believe and that he did believe, from facts found by officers and employees of the Food and Drug Administration, that the labeling of said drug Pso-Ridisal would be and was in a material respect misleading to the injury or damage of the purchaser or consumer.

"3. The actions of defendants complained of by plaintiffs herein were not illegal, were not in excess of the authority vested in defendants by law, and did not constitute an abuse of lawful duty.

"4. The petition filed by plaintiffs herein does not disclose any cause of action against the defendants named therein since said defendants do not and are not authorized to institute libel for condemnation or other suits in any court of the United States, and there is no mandatory duty vested in United States Attorneys or the Department of Justice to institute libel for condemnation or other suits on referral by or recommendation of defendants.

"5. The plaintiffs herein have not established that they have suffered or will suffer any irreparable or legal injury by the institution of libel for condemnation actions under the Federal Food, Drug, and Cosmetic Act against their product Pso-Ridisal.

"6. Since the petition filed by plaintiffs herein sought to restrain defendants, officials of the Federal Government, from performing their statutory functions, the action instituted by plaintiffs herein was a suit against the United States which had not consented to be sued, and this Court does not have jurisdiction of the subject matter of this action.

"7. The petition filed by plaintiffs herein establishes no grounds for equitable relief and fails to state facts which entitle the plaintiffs to the relief sought by them.

"8. The motion made by plaintiffs herein for a preliminary injunction should be denied.

"9. The motion made by defendants herein to dismiss this action and for summary judgment should be granted.

"Let the foregoing Findings of Fact and Conclusions of Law be filed, and order and decree be entered accordingly."

#### DRUGS FOR VETERINARY USE\*

**2141. Misbranding of Federal Swine Compound. U. S. v. Joseph Borkovec (Federal Chemical Co.).** Plea of not guilty. Tried to the court and jury. Verdict of guilty. Fine, \$500 and costs. (F. D. C. No. 17843. Sample Nos. 19227-H, 19228-H.)

**INFORMATION FILED:** April 12, 1946, Northern District of Illinois, against Joseph Borkovec, trading as the Federal Chemical Company, Willow Springs, Ill.

**ALLEGED SHIPMENT:** The product, together with a number of leaflets entitled "Information Blank" and a number of pamphlets entitled "Stop Hog Losses," was shipped from the State of Illinois into the State of Iowa. The product was shipped on or about March 27, 1945, and the leaflets and pamphlets were shipped on or about March 5, 1945.

**LABEL, IN PART:** "Federal Original Swine Compound An All Liquid Hog Medicine \* \* \* Oats Medicine \* \* \* Drinking Water Medicine \* \* \* Jess W. Jones, Willow Springs, Illinois (Owner and Producer Since 1917) Formerly Federal Chemical Company, Omaha, Nebr."

**NATURE OF CHARGE:** *Oats Medicine* and *Drinking Water Medicine*. Misbranding, Section 502 (a), the label statements "An All Liquid Hog Medicine \* \* \* A Tested Prescription \* \* \* Treatment Consists of Two Different Medicines, Oats Medicine [or "Drinking Water Medicine"]," as well as certain statements in the leaflets and pamphlets which accompanied the articles were false and misleading since they represented and suggested that the articles when used in combination would be efficacious in maintaining hogs in good condition and in bringing back to normal condition hogs which were not in good condition; that the articles would be efficacious in the prevention and treatment of necro, "bull-nose" or sniffles, necrotic enteritis, scours and bloody scours, "flu," swine plague, pneumonia, typhoid and paratyphoid infections in hogs, mixed infections, and parasites and worms; that they would be efficacious in the treatment of sick hogs and would stop hog losses; that they would aid in the correction and prevention of swine diseases; that they would go directly to the source of the disease; and that they would assure hog health. The articles would not be efficacious for the purposes stated or implied.

**DISPOSITION:** On May 5, 1947, the defendant having entered a plea of not guilty, the case came on for trial before a jury and resulted in a verdict of guilty. On May 16, 1947, the court imposed a fine of \$250 on each of the 2 counts of the information.

\* See also No. 2114.